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10/687,135	10/15/2003	Ivan Osorio	539.3167.1	8261

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Fredrikson & Byron, P.A.
Intellectual Property Group, MDT Patents
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402

EXAMINER
ALTER, ALYSSA MARGO

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
06/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@fredlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,135	OSORIO ET AL.	
	Examiner	Art Unit	
	ALYSSA M. ALTER	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 7, 2011 have been fully considered but they are not persuasive. The Applicant argues that “Shaw’s above described tests, concerning ensuring that measured pulses are actually delivered within acceptable tolerance ranges (i.e. pulse width and frequency tolerances), are hardware self-tests to see that the circuitry can reform as specified. Hardware test to determine whether the device can actually perform within a specific parameter does not constitute “assessing whether the first set of information [received from a user] is within a rage of safety”."

2. However, while Shaw et al. does disclose “hardware self-tests”, these self-tests are not what is considered to be the "first set of information". The examiner refers to the tests during the application of the ECT treatment once the system successfully passes the self-test. “If all these hardware self-tests are preformed without error, the system enters the armed state 506" (col. 29, lines 30-31). “In the armed state 506, the system detects the treatment button has been pressed, the system begins applying the actual ECT treatment pulse train in step 508. The parameters of the ECT treatment pulse train are those specified by the user via the front panel"(col. 29, lines 37-41). Therefore, the information monitoring is not during the self-test but when “the system begins applying the actual ECT treatment pulse train in step 508”.

3. Additionally, Shaw et al. discloses that the parameters of the ECT treatment pulse train are “current, pulse width, frequency and duration” (col. 29, line 42). Furthermore, "the system according to the invention monitors each of these parameters

during the treatment and terminates the treatment if any one of these parameters, as well as others, deviates from specific or predetermined values of these parameters. This avoids harm to the patient" (col. 29, lines 43-48). Therefore, Shaw et al. monitors and assesses "whether the first set of information is within a range of safety" by ensuring the parameters do not deviate from the specific or predetermined values.

4. Therefore, the system of Shaw et al. does receive “a first set of information from a user, the first set of information being associated with the first therapy configuration” (col. 29, lines 30-49). Therefore, the pending claims remain rejected under Shaw et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, 12-16, and 20-37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. (US 6,014,587). Shaw et al. discloses a method for configuring and testing therapy parameters for treatment of a nervous system disorder, by receiving a first set of information form the user, where in the first set of information is associated with the therapy configurations and assessing whether the information is within a range of safety (col. 30, lines 20-25 and lines 31-34) and if it is not safe, modifying the treatment information (col. 19, lines 24-30).

6. As to claim 1, Shaw discloses a medical system "the medical device system being in a manual treatment therapy mode, the method comprising: (a) receiving a first set of information from a user the first set of information being associated with a first treatment therapy configuration (col. 29, lines 39-42 and col. 30, lines 35-37; where the user inputs the treatment pulse parameters); (b) assessing whether the first set of information is within a range of safety (col. 30, lines 20-23, the pulse width is measured and compared to the specified pulse width to assess whether it is within an acceptable tolerance or range of safety; and col. 30, lines 37-40, the current and voltage must be within a specific range of acceptable values); (c) applying a first treatment therapy to a patient in accordance with the first set of information (col. 4, lines 19-26; stimulation pulses are administered to the patient and measured to ensure that they are within an acceptable range); (d) if the first treatment therapy is not safe, executing a corrective action (col. 30, lines 24-25; if the pulse width is outside of the safe range, the safety processor terminates the treatment. The therapy is compared to tolerable or safe values and if it falls outside of the range the therapy corrected by termination); and (e) if the first treatment therapy is safe, storing the first set of information for subsequent use (col. 7, lines 26-40; the system is a computer system the coordinates four processors. If the signals administered are within the range of safety they are stored by the computer system and the re-administered to the patient).

7. As to claim 2, the corrective action comprises "preventing re-delivery of the first treatment therapy". Since the treatment is terminated if it falls outside of the acceptable range, it is prevented from being redelivered (col. 30, lines 24-25).

8. As to claims 3, the corrective action comprises “terminating the first treatment therapy” (col. 30, lines 24-25).

9. As to claims 4 and 26, the treatment is compared to an acceptable range to determine “whether the first treatment therapy is tolerable to the patient”. The system receives the acceptable values from the user (col. 29, lines 39-42 and col. 30, lines 35-37) and compares the actual values to the acceptable values. Furthermore, “the executing a corresponding action” is the termination of treatment when the treatment is deemed not safe (col. 30, lines 24-25).

10. As to claims 6 and 27, the examiner considers the time stamp placed on the pulse width (col. 30, lines 15-18) is considered to be the “associating a first label with the first set of information”.

11. As to claims 5 and 7, since the system monitors the pulse width and provides a label (i.e. time stamp), the system senses information received by the user and places a label according to the information. Each subsequent therapy pulse has a pulse width receives a label unique to it (since it’s time stamped). The system continues to deliver pulses unless termination and thus the system applies “a subsequent treatment therapy in accordance with the first set of information”.

12. As to claim 12, “the first therapy comprises at least one attribute selected from the group...stimulation parameter,…. an indication about safety to the patient and a level of tolerability by the patient” (col. 29, lines 41-49; Information that is received from the user information about a stimulus parameter and assesses whether the treatment therapy will be safe and tolerable to the patient).

13. As to claim 13, “the stimulation parameter is selected from the group…..voltage level of a stimulation pulse, a pulse width of the stimulation pulse, duration of a stimulation pulse train..." (col. 30, lines 22-25, the pulse width of the stimulation pulse is a sensed stimulation parameter as well as the duration; and col. 30, lines 37-40, the voltage must be within a specific range of acceptable values).

14. As to claims 14 and 32, “the first set of information comprises a voltage level of a stimulation pulse, a pulse width of the stimulation pulse"(col. 30, lines 22-25 and col. 30, lines 37-40). Shaw et al. discloses specific parameters (col. 4, lines 33-40) and sensing electrode interface impedance (col. 6, lines 48-56) and does not provide stimulation or treatment commencement if there is a detected error (col. 29, lines 30-36).

15. “(f) determining a surface area of the electrode; (g) determining a charge density that is associated with the electrode; and(h) if the charge density is greater than a predetermined threshold, rejecting the first set of information in order that the first treatment therapy corresponding to the first set of information is not delivered to the patient”. Determining impedance, as done by Shaw et al. in col. 6, lines 48-56, determines surface area of the electrode, charge density and compares charge density to a threshold to prevent stimulation or treatment commencement if there is an error.

16. As to claim 15, Current density is the distribution of electric current per unit of area. Therefore, the “charge density” would necessarily be “approximately equal to the current multiplied by the pulse width of the stimulation pulse divided by the surface area of the electrode”.

17. As to claim 16, According to Ohm's law, current is equal to voltage divided by resistance. Therefore, the current would necessarily be "approximately equal to the voltage level of the stimulation pulse divided by the impedance of the electrodes".

18. As to claim 20, "wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and psychiatric disorder". ECT stimulation is used to treat nervous system disorders such as psychiatric disorders that affect mood and/or anxiety (col. 1, lines 49-67).

19. As to claim 21, "wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia". ECT stimulation is used to treat nervous system disorders such as psychiatric disorders that affect mood and/or anxiety (col. 1, lines 49-67). Furthermore, the examiner considers schizophrenia to affect mood and anxiety.

20. As to claim 22, ECT is electrical stimulation (Electro-convulsive therapy). Therefore, "the first treatment therapy is selected from the group consisting of electrical stimulation".

21. As to claim 23, "the first treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve". Treatment that affects the nervous system would *necessarily* affect the brain, spinal cord, vagal nerve *or* peripheral nerve since there isn't a nerve that would not fall into one of these categories.

22. As to claim 24, "the medical device system is selected from the group consisting of an external system, an implanted system, and a hybrid system". The system would necessarily meet this limitation, since the system is either totally implanted, totally external or a combination therefore. There is no additional implantation possibility for medical devices. Therefore, the system of Shaw et al. meets this limitation.

23. As to claim 25, "a user interface (18 in figure 1B); a treatment therapy module (the ECT block, depicted as 56 in figure 1A, col. 8, lines 1-4, dispenses the ECT pulses and is thus the therapy treatment module); a memory (col. 8, lines 63-66); and a processor (depicted in figure 2) that is connected to the user interface in order to receive a command from a user and to send a response to the user and that instructs the treatment therapy module, the processor configured to perform: (a) receiving a first set of information from the user through the user interface, the first set of information being associated with a first treatment therapy configuration(col. 29, lines 39-42 and col. 30, lines 35-37; where the user inputs the treatment pulse parameters); (b) assessing whether the first set of information is within a range of safety; (col. 30, lines 20-23, the pulse width is measured and compared to the specified pulse width to assess whether it is within an acceptable tolerance or range of safety; and col. 30, lines 37-40, the current and voltage must be within a specific range of acceptable values); (c) applying a first treatment therapy to a patient through the treatment therapy module in accordance with the first set of information (col. 4, lines 19-26; stimulation pulses are administered to the patient and measured to ensure that they are within an acceptable range); (d) if the first treatment therapy is not safe, executing a corrective action(col. 30, lines 24-25; if the

pulse width is outside of the safe range, the safety processor terminates the treatment. The therapy is compared to tolerable or safe values and if it falls outside of the range the therapy corrected by termination); and (e) if the first treatment therapy is safe, storing the first set of information in the memory, wherein the first set of information is accessible for a subsequent treatment therapy (col. 7, lines 26-40; the system is a computer system the coordinates four processors. If the signals administered are within the range of safety they are stored by the computer system and the re-administered to the patient).

24. As to claims 34-37, the system employs a safety processor to execute the safety monitoring (col. 7 lines 57-67) and a memory (col. 8, lines 63-66), therefore the monitoring is executed from a computer and thus computer readable medium. As such "a computer-readable medium" executes "instructions for performing the method recited".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 18-19 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shaw et al. (US 6,014,587). Shaw et al. discloses applying a muscle relaxant prior to the ECT treatment (col. 31, lines 29-

33). The examiner considers the administering of a muscle relaxant to be a drug infusion.

26. In the alternative, Shaw et al. discloses the device substantially as claimed except for explicitly reciting that the muscle relaxant is administered through drug infusion. It would have been obvious to one having ordinary skill in the art at the invention was made to modify the means of delivering the drug to the patient through infusion in order to provide the predictable results of modifying the administration of the muscle relaxant to meet specific patient needs and requirements. Furthermore, drug infusion is a well know means for administering a drug to a patient.

27. Claims 8-11, 17, 28-31 and 33 stand rejected under 35 U.S.C. 103(a) as obvious over Shaw et al. (US 6,014,587). Shaw et al. discloses the device substantially as claimed but fails to teach “receiving another set of information for the user”. Shaw et al. only receives a first set of parameters from the user and does not received an updated set of information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECT treatment device of Shaw et al. to include a means for checking to see if additional data parameters have been set or prompting the user if they would like to modify the parameters in order to provide the predictable results of modifying the treatment to meet specific patient needs and requirements. Additionally such procedures would enable a user to modify treatment as it is occurring without having to terminate treatment and reset the ECT device, thus causing less disruption to the treatment and the patient.

28. As to claims 8 and 28, each pulse width is assigned a time stamp or label. Therefore any subsequent pulses are assigned an associated label for the additional set of information and then compared. Thus the pulse widths are compared by "comparing the first set of information and the second set of information".

29. As to claims 9 and 29, since the pulse widths and coordinating labels are compared and stored, the therapy configurations information is stored regardless if it is "essentially unique" or "not essentially unique". Therefore, Shaw et al. does store essentially unique information. Furthermore, since it is compared (col. 30, lines 20-25) it will inform the user if it is not unique and thus in the tolerable range or if is unique and thus out of the tolerable range.

30. As to claims 10-11 and 30-31, additionally, if the data "is not essentially unique" and thus is outside of the tolerable range, the system will notify the user and reject further administration of the stimulation by terminating therapy.

31. As to claims 17 and 33, as stated above, Shaw et al. discloses the device substantially as claimed except for receiving subsequent set of information from the user. The examiner considers the "run mode" to be the execution of the therapy. "(f) transitioning operation to a run mode; (g) receiving a subsequent set of information from the user, the subsequent set of information being associated with a subsequent treatment therapy configuration; and (h) if the first treatment therapy is not acceptable and if the subsequent set of information corresponds to a subsequent treatment therapy that exceeds a corresponding level of tolerance associated with the first treatment therapy, rejecting the subsequent set of information". Additionally since the safety

monitor monitors, voltage, current and pulse width of the administered stimulation, the system necessarily a subsequent therapy configuration.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ALYSSA M. ALTER/
Examiner
Art Unit 3762

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762